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Supreme Court, U.S.
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IN THE

Supreme Court of the United States

APOTEX USA, INC.,

Petitioner,

v.

MERCK & CO., INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF

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Even if it were reasonable to find the facts as Merck & Co., Inc. ("Merck") has set them out (and that would be against the weight of the evidence), that would not justify the entry of summary judgment below in the face of the evidence of intentional suppression and concealment advanced by Apotex USA, Inc. ("Apotex"). It is a fact of life that the type of pharmaceutical here at issue is an item of global commerce. When dealing with international commerce, it is an unreasonable departure from the normal course of judicial proceedings for the courts of this country to turn a blind eye to inconsistencies between a position asserted by a litigant in this country and positions on which it has prevailed in a foreign country. Certiorari is an appropriate vehicle with which to remedy this inequity.

I. Merck's Inconsistency Is One Reason To Grant Certiorari.

Merck maintains that it was not inconsistent for it first to persuade a Canadian court that no chemical reaction occurs in the process it uses, then to assert in a United States court that its earlier denial was actually a *disclosure* of that very process. That conduct by one tentacle of a multi-national drug company has implications far beyond this one case. The conduct of such companies is not only central to modern global commerce; it also impacts on basic human rights throughout the world. Our federal courts cannot simply wink at Merck's hypocrisy here. To do so undermines the constitutional purpose of our patent system, to promote the progress of the useful arts.

As acknowledged in *Aetna Ins. Co. v United Fruit Co.*, 304 US 430 (1938), conflicts with the decisions of a foreign court *can* be a proper basis for certiorari. As Merck notes on pages 21–22 of its Brief in Opposition, the particular issue in that case concerned a point of maritime law — but nothing in the decision limits it to that field. In the case at bar, the inconsistency is much more profound. Merck prevailed in persuading the Canadian court that no chemical reaction occurred in making its pharmaceutical. That chemical reaction (which Merck denied) is exactly what Apotex claimed in its U.S. patent application. Summary judgment effecting a forfeiture of Apotex's federal property right simply cannot be an

appropriate mechanism under the Federal Rules of Civil Procedure for resolving such a dispute. Certiorari should therefore be granted, the judgment below should be vacated, and the case should be remanded for further proceedings.

II. Merck Suppressed and Concealed the Invention.

A. Merck Intentionally Suppressed and Concealed

The important substantive issue of patent law in this case is not *disclosure*; it is Merck's intentional *suppression* and *concealment*. While disclosure is related to suppression and concealment, it is not the same thing or even a flip side of the same coin.

The central thing, the "it" that is the invention covered by this patent, is a chemical reaction. In the Canadian suit Merck *denied* that "it" occurred. Dr. Sherman, the inventor for Apotex, realized that Merck was not telling the truth. He knew that "it" (the chemical reaction) did occur, and he so testified in the Canadian court.

Merck, however, prevailed in its false denials in Canada. It told the big lie, and got away with it. That ill-gotten triumph in the Canadian court typified Merck's suppression and concealment before and up to that time. Faced with the conflicting evidence of (1) Dr. Sherman explaining that the reaction occurred and (2) Merck's bald-faced denial, MacKay, J., ruled:

> The difficulty encountered is said to be that including the compound enalapril maleate, here said to be the active ingredient, in both VASOTEC and APO-ENALAPRIL, with regularly accepted adjuvants, as the patent indicates, presented a major problem in assuring stability of the product and avoiding undue disintegration. Dr. Sherman, who was directly responsible for overseeing product formulation at Apotex, said that in his experience the development of a product for consumption in dosage form where the active ingredient was comparatively small

was a "no-brainer", easily accomplished. In this particular case, however, he had encountered the most difficulty of any product development in his experience. From document production by Merck, for counsel's eyes only by agreement, it was apparent that addition of one common adjuvant, sodium carbonate or sodium bicarbonate, was a part of Merck's tablet development and questions were asked in the course of discovery about this. Questions were also raised at trial, of Dr. Schwartz, an expert appearing for the plaintiffs, and Drs. Niebergall and McClelland, experts for the defendant. *The questions sought confirmation that the Merck process of tablet formulation may well have been inventive in the manner of its resolution of the problem of disintegration, by producing a reaction through use of sodium carbonate or bicarbonate, and water, that solved the stability problem but left something other than enalapril maleate as the active ingredient. None of the experts could confirm this was the inevitable result of the information provided to them, though all confirmed that depending upon the process of mixing and the relative volume of water mixed, a reaction could be expected.*

Merck & Co. Inc. v. Apotex Inc., No. T-2408-91, 59 C.P.R. (3d) 133, 181, 1994 C.P.R. LEXIS 2122, *113–*115 (Fed. Ct., Dec. 14, 1994), *reprinted at* L58 (emphasis added).

This statement by Judge MacKay is even more than a finding of suppression and concealment — it is the actual fruits of that suppression and concealment itself. Merck's deception of Judge MacKay (about the reaction that did in fact occur) helped it to prevail in the Canadian litigation.

Apotex adduced more than enough evidence in affidavits to raise a genuine issue as to the material fact of suppression and concealment. One expert, Dr. Scheindlin, specifically stated in his declaration, "Mr. McLeod's use of the word 'stabilizer' in his 1994 testimony *is deceptive*. Sodium bicarbonate does not act as a stabilizer *per se*, but rather is an important ingredient of a chemical reaction to convert enalapril maleate to enalapril sodium."

(emphasis added). Similarly, a declaration from Dr. Sherman established that McLeod's testimony *concealed* that the water being added would produce a chemical reaction, and thus *suppressed* the aspect of the process that the Apotex patent identifies as a critical improvement over the prior art.

The clincher showing Merck's suppression and concealment is its own internal document admitting its motive for its deception. Merck admitted, "[W]e have a major concern regarding the presence of a statement on the product label which infers the formation of a sodium salt of enalapril maleate. *Such a statement might affect worldwide registration of the product and existing approved labeling.*" The "formation of a sodium salt of enalapril maleate" is the chemical reaction that is the "it" of the invention in suit. That is exactly the reaction that Merck could not afford to admit, because it would jeopardize "worldwide registration of the product and existing approved labeling." In fact, and despite the arguments in its brief implying the contrary, Merck did *not* disclose that critical fact.

B. Merck's Alleged Disclosures Did *Not* Disclose the *Invention*.

Merck did *not* disclose at all the *true* process it used to manufacture its drug, either in the Canadian litigation or before. In the true process that Merck actually uses, during the course of mixing the ingredients with water, a reaction is caused between enalapril maleate and sodium bicarbonate to convert the enalapril maleate to enalapril sodium.

During the Canadian trial and before, Merck made *no* disclosure *whatsoever* of this reaction. Instead, Merck suppressed and concealed the crucial fact: that this reaction occurred. Before the Canadian trial, Merck had concealed this information by incomplete, inaccurate, false, and misleading submissions to regulatory authorities such as the Food and Drug Administration. During the trial, it concealed that fact even from its own paid expert witness, Dr. Schwartz.

Merck's VASOTEC tablets are falsely labeled as containing enalapril maleate when, in fact, they contain enalapril sodium. Contrary to Merck's assertions in the courts below, the label on a pharmaceutical is not meant to list the starting ingredients in a process. Instead, it is supposed to list the *results* of any reaction, identifying exactly what is in the tablet being put in to the patient's body. Apotex established this fact below with declarations submitted in opposition to Merck's summary judgment motion. If Merck were correct (it is not), and if a pharmaceutical label were meant to identify starting ingredients (it is not), then Merck's label would nonetheless be deficient because that label does not identify all of the critical ingredients such as, for example, water. The omission of such a critical starting ingredient is further evidence showing that the pharmaceutical label was supposed to list not the starting ingredients, but instead the *results* of any reaction to identify the actual ingredients comprising the tablet a patient will ingest.

III. Dr. Sherman's Inventive Insight Does Not Negate Merck's Suppression and Concealment.

Dr. Sherman, Chairman of Apotex, is an expert in pharmaceutical formulation and has received patents for numerous inventions. Yet even Dr. Sherman, who has more than ordinary skill in this art, was deceived for several years by Merck's mislabeling of its drug. Dr. Sherman had tried to replicate Merck's tablets, but found that tablets he made containing enalapril maleate (not as a starting ingredient but instead, as listed on Merck's label, as part of the final tablet) were unstable. When Dr. Sherman learned more details about Merck's initial ingredients, he knew that its product labeling was false. He independently invented the process of causing the critical reaction. Merck, however, continued to *deny* that any such reaction occurred.

During the Canadian litigation it was Dr. Sherman, and not Merck, who disclosed that a reaction must be occurring. This point is critical. *Dr. Sherman made the only disclosure of a reaction, which disclosure* a fortiori *must have occurred after Dr. Sherman came up with the invention himself.* There was no disclosure by Merck of any reaction, and no disclosure of that reaction by anyone

before Dr. Sherman independently invented it and so testified in the Canadian proceedings.

One of Apotex's attacks upon Merck's Canadian patent was that it failed to disclose that a reaction was needed in order to get a stable tablet. Not only did Merck fail to disclose and refuse to admit that there was a reaction and that the tablets contained enalapril sodium and not enalapril maleate, but also Merck's own experts on cross-examination refused to admit that conversion to enalapril sodium necessarily occurred. Assuming that Merck's expert in the Canadian litigation testified truthfully, his testimony merely proves that Merck *concealed the fact that a reaction occurred even from its own paid expert.*

IV. Apotex Did Not Waive Its Arguments under § 282, Which Are Applicable Here.

Apotex's invocation of § 282 was not a new argument in the Federal Circuit and is not a new argument here. Apotex sought in the District Court to have Merck identify the individual whom it alleges invented the process at issue. That identification, which Apotex timely sought in the District Court, is exactly what § 282 requires.

Merck's argument that § 282 is applicable only at trial and not on summary judgment would lead to the anomalous result that a case could be decided in the posture of summary judgment based on evidence that could not be presented at trial. That is not the law. While evidence submitted in response to a summary judgment motion need not be in the *form* at which it would be adduced at trial,[1] that evidence still must be such that it would be *admissible* at trial. The entire point of the summary judgment procedure is to determine whether there exists a genuine issue for trial. The question is whether a jury could properly find in favor of the non-movant. A trial cannot be avoided on the basis of evidence that a party could not present.

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[1]For example, witness testimony may be offered by affidavit or declaration instead of direct examination and cross.

Merck suggests on page 19 of its Reply that this case is somehow special because the allegedly prior invention is the same process accused of infringement. Contrary to Merck's implication, that circumstance is not unusual. It is typical. It is exactly what § 282 was intended to address.

Finally, Merck asserts that the application of § 282 is within the discretion of the District Court. While that may be, here there is no indication on the record that the District Court purported to exercise such discretion. Instead, it simply ignored this statutory requirement.

V. Merck's Disclosures that Never Reached the United States Are Not Sufficient To Negate Its Suppression and Concealment.

Cases that Apotex cited in its petition interpret § 102(g) as requiring that the alleged prior inventor (Merck) prove that the public has gained knowledge of the invention. *Palmer v. Dudzik*, 481 F.2d 1377, 1387 (C.C.P.A. 1973). As explained in Apotex's petition, that interpretation is necessary to effectuate the Constitutional purpose of the patent laws.

This Court has explained the Constitutional standard authorizing and limiting the U.S. patent laws as follows:

> At the outset it must be remembered that the federal patent power stems from a specific constitutional provision which authorizes the Congress "To promote the Progress of ... useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their ... Discoveries." Art. I, § 8, cl. 8. The clause is both a grant of power and a limitation. This qualified authority, unlike the power often exercised in the sixteenth and seventeenth centuries by the English Crown, is limited to the promotion of advances in the "useful arts." It was written against the backdrop of the practices — eventually curtailed by the Statute of Monopolies — of the Crown in granting monopolies to court favorites in goods or businesses which had long before been enjoyed by the public. *See* MEINHARDT, INVENTIONS, PATENTS AND

> MONOPOLY, pp. 30–35 (London, 1946). The Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby. Moreover, Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available. Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must "promote the Progress of ... useful Arts." This is the *standard* expressed in the Constitution and it may not be ignored. And it is in this light that patent validity "requires reference to a standard written into the Constitution." *A. & P. Tea Co. v. Supermarket Corp.*, *supra*, at 154 (concurring opinion).

Graham v. John Deere Co., 383 U.S. 1, 5–6 (1966) (footnote omitted).

Merck asserts that, under its interpretation of the statute, the alleged prior inventor need not prove (in order to negate its suppression and concealment) that anyone in the United States public actually possessed the information. Merck does not explain how to reconcile its interpretation (which inhibits progress of the useful arts by encouraging suppression and concealment until one suspects that others may be getting close) with the Constitutional *standard* set forth in *Graham*. The "plain text" of such a statute cannot overcome the requirements of the Constitution.

But even if Merck's interpretation were consistent with that standard (it is not), Merck's proposed rule has nothing to do with the facts of this case. Not only did the United States public here not have possession of the alleged prior invention, *there was no reasonable chance of that information getting to the United States*. The counterexamples Merck suggests, of foreign patents and the like, are inapposite. A foreign patent is, presumptively, readily available to the United States public. The misleading testimony of

Merck's witness narrating a silent video in a Canadian courtroom is in no such sense accessible. Accordingly, Merck (as the party that was found to have suppressed and concealed its invention) should be required to prove that its subsequent acts negating suppression and concealment were at least such that it might have been reasonably possible for the United States public to gain the benefit of those disclosures.

VI. Merck's Reliance on What It Calls Factual Findings Begs the Question of Why the Courts Below Were Making Findings on Summary Judgment in the First Place.

A recurring theme of Merck's Brief in Opposition is that the courts below looked at all the evidence and found the facts adversely to Apotex.

That is the point.

This case was submitted on motion for summary judgment. The lower courts here were not supposed to be weighing evidence. They were not supposed to be finding facts. Instead, at this juncture, all factual issues should have been resolved in Apotex's favor. They were not.

CONCLUSION

Patents for inventions are a critical aspect of the pharmaceutical industry, which is increasingly characterized by the global conduct of multinational corporations. This case is simply about the fact that such a multi-national company should not be permitted to suppress and conceal an invention up until and including a trial in a foreign court, then (when another inventor nevertheless discovers the advance) invalidate that inventor's patent. Even if Merck did develop this process first, Apotex deserved its patent for Dr. Sherman's invention because all the way through the trial in Canada Merck continued to suppress and conceal the hidden chemical reaction that is the subject matter Dr. Sherman invented and Apotex patented. Merck mislabeled its product, withheld information about the reaction even from its own expert witness in Canada, and convinced the Canadian court that no

reaction necessarily occurred. To allow Merck then to rely on this pattern and practice of deception to negate its suppression and concealment is so far a departure from the accepted and usual course of judicial proceedings by the court of appeals and the district court as to call for an exercise of this Court's supervisory power.

Respectfully submitted

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